

REMARKS

In reply to the Office Action dated January 25, 2005, claims 21-25 are currently under examination in the Application. By the above amendment, claim 22 has been canceled, and claims 21, 23, and 24 have been amended. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

***Priority Date***

Applicants acknowledge that the Examiner has determined that the effective priority date of the instant application is April 27, 2000. The specification has been amended as recited above to reflect this priority date.

***Claim Rejections Maintained – 35 U.S.C. § 112***

Claims 21 and 23 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner asserts that claims 21 and 23 lack written description sufficient to support the entirety of the claimed genus of polypeptides having at least 90% identity to SEQ ID NO: 809 (L552S), given the large number of species that fall within the claimed genus, and in light of the fact that the biological function of L552S is not recited in these claims. Essentially, the Examiner asserts that the instant specification does not disclose enough representative species to support the claimed genus.

Applicants respectfully traverse this basis of rejection and submit that the instant application provides adequate written description to support claims 21 and 23 and demonstrate that Applicants had possession of the claimed invention at the time of filing the instant application. Applicants submit that the number of possible species that fall within the claimed genus is not so large that the skilled artisan would not clearly recognize such a species and

appreciate that it was in Applicants' possession at the time of filing, based upon the disclosed L552S sequence of SEQ ID NO:809. Applicants reiterate that the skilled artisan would immediately appreciate that Applicants had possession of such variants, in light of the teaching of the instant specification regarding the functional uses of such polypeptides in diagnostic and therapeutic applications that do not require biological function, including, *e.g.*, the detection of L552S-specific antibodies in patient serum and the generation of L552S antibodies and T cells. In addition, Applicants note that any species within the claimed genus could be readily identified by the skilled artisan, using basic sequence comparison software, which is widely and publicly available, including the programs described in the instant application, *e.g.*, on page 82, line 7, to page 84, line 3. Accordingly, the large number of species that fall within the claimed genus do not, in any manner, limit the skilled artisan's ability to recognize a claimed species or understand it to have been in Applicants' possession at the time of filing the instant application.

Nonetheless, without acquiescence to this basis of rejection, claim 21 has been amended to specifically recite the identifying feature that the claimed L552S polypeptides are overexpressed in lung cancer tissue. Support for this amendment is provided throughout the specification as filed, including, *e.g.*, on page 75, lines 1-13.

Applicants submit that the instant specification provides more than adequate written description to support the genus of polypeptides that have at least 90% identity to SEQ ID NO:809 and are overexpressed in lung tumor tissue. Under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics. Applicants submit that the instant application clearly describes identifying characteristics sufficient to show that Applicants were in possession of the claimed genus of L552S-related polypeptides, including their overexpression in lung tumor tissue.

The Examiner has cited Example 14 of the Written Description Training Materials promulgated by the Patent and Trademark Office as an example of appropriate identifying characteristics. The claim in this example is drawn to a genus of polypeptides having at least 95% identity to a recited sequence and which catalyze a particular reaction. According to

the Training Materials, such a claim is deemed described when the specification conveys to the skilled artisan that a functional description of the protein essential to the operation of the claimed invention is recited in the claim, and the specification describes an assay that will identify other proteins having the claimed activity, such that one skilled in the art would recognize that proteins which comprise the same identity but do not have the recited function would not be embraced by the claim.

Applicants submit that the instant specification provides written description of the instant claims that is analogous to that described in Example 14 and, therefore, provides adequate written description under Section 112. Applicants disagree with the Examiner's assertion that the situation of the instant application is not analogous to the situation described in this example, since the biological function of the L552S polypeptide is not described in the instant specification. To the contrary, Applicants submit that the claims of the instant application are even more fully supported by the instant specification than the claims described in the example.

The instant claims recite the functional characteristic that the claimed polypeptides are overexpressed in lung cancer. Applicants submit that functional characteristics are not meant to be limited to biological activity *per se*, particularly when such biological activity is not relevant to the purpose of the claimed invention. Regarding the relevant characteristic that the claimed polypeptides are overexpressed in lung cancer, Applicants note that the instant specification provides numerous assays to determine when a polypeptide is overexpressed in lung cancer tissue, including antibody-based assays, as described, *e.g.*, on page 152, line 23, to page 159, line 2. Clearly, overexpression in lung cancer tissue is an important and identifying feature of the L552S polypeptides, which provides the basis for the usefulness of L552S-related polypeptides and fragments thereof. Furthermore, determining whether an L552S polypeptide or variant thereof is overexpressed in lung tumor tissue requires merely routine testing by the skilled artisan. Indeed, determining the expression levels of a polypeptide is arguably, at least in many cases, a simpler procedure than determining whether a polypeptide variant possesses enzymatic activity, as described in Example 14. Accordingly, Applicants submit that the instant specification provides adequate description of the claimed invention.

In light of the above amendments and remarks, Applicants respectfully request the Examiner reconsider and withdraw this basis of rejection.

***New Claims Rejections – 35 U.S.C. § 112***

Claim 22 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner asserts that the instant specification fails to provide an adequate number of representative species or identifying characteristics to provide written description of the entire genus claimed.

Without acquiescence to this basis of rejection, and solely to expedite prosecution of the instant application, claim 22 is cancelled, thereby obviating this basis of rejection. Claim 23 has been amended to depend solely from claim 21. Applicants respectfully request that the Examiner withdraw this basis of rejection.

***New Claims Rejections – 35 U.S.C. § 102***

Claim 24 stands rejected as allegedly being anticipated under 35 U.S.C. § 102 over Bevan *et al.* (Accession No. CAB83295, publicly available March 2000), in light of Hoffman *et al.* (U.S. Patent No. 5,095,093, issued March 10, 1992). Specifically, the Examiner asserts that Bevan *et al.* describes a polypeptide having four residues in common with SEQ ID NO:809, while Hoffman *et al.* teaches that an immunogenic portion may comprise as little as four amino acid residues.

Without acquiescence to this basis of rejection, claim 24 has been amended to recite the feature that the claimed polypeptide comprises at least ten consecutive amino acid residues of the sequence of SEQ ID NO:809. Support for this amendment is provided in the instant application, including, *e.g.*, on page 77, lines 5-9. Applicants submit that Bevan *et al.* fails to describe a polypeptide having at least ten consecutive amino acid residues of the sequence of SEQ ID NO:809 and, therefore, fails to anticipate this claimed polypeptide.

Applicants respectfully request that the Examiner withdraw this basis of rejection, in light of the present amendment.

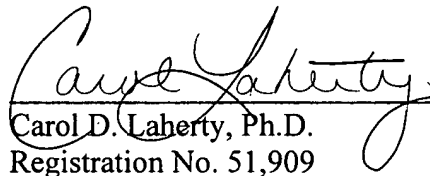
Applicants further submit that the instant specification provides support under Section 112 for the polypeptides recited in amended claim 24. Specifically, Applicants submit that the instant specification describes a sufficient number of representative species having the claimed characteristics, including those specifically identified in claim 25. In addition, the specification describes the recited characteristic that the claimed polypeptides are immunogenic, in addition to providing methods of determining whether a polypeptide is, indeed, an immunogenic portion of SEQ ID NO:809, including those provided on page 75, line 24, to page 76, line 7. Accordingly, the instant specification provides written description of the claimed genus of polypeptides, under the criteria of the Examination Guidelines set forth by the Patent and Trademark Office.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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